

REMARKS

Claims 1, 10, 12 and 32-33 have been amended.

Claims 4 and 11 have been canceled.

Claim 34 has been added.

To the extent that it is not necessary to address rejections of dependent claims to provide a complete response to the Office Action, the choice not to discuss such rejections is not, and cannot be interpreted as, acquiescence to such rejections, nor can it be construed to limit the scope of any claims that may issue in this patent application or in any patent application claiming priority thereto.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claims 1-3, 5-10, 12-13 and 30-34

Claim 1 has been amended to include, among other limitations, the limitations previously set forth in claim 11, and claims “[a] surgical method for manipulating a graft vessel relative to a target vessel, comprising: making a substantially longitudinal incision in a wall of the graft vessel at an end thereof to form a flap therein; providing a staple holder having spaced-apart arms, a graft affixer projecting therefrom, and a plurality of discrete connectors held by said staple holder, each said arm independently holding at least one said discrete connector; placing a portion of the graft vessel between said spaced-apart arms; engaging the graft vessel with said graft affixer; placing the flap

against an outer surface of the target vessel; and affixing the end of the graft vessel to the target vessel.”

In contrast, U.S. Pat. No. 4,930,674 to Barak (“Barak”) neither teaches nor suggests each and every limitation of amended claim 1. First, Barak fails to teach or suggest the claimed “making a substantially longitudinal incision in a wall of the graft vessel at an end thereof to form a flap.” (emphasis added). The Office Action admits that “Barak does not disclose forming a longitudinal incision in a wall of the graft vessel,” such that Barak does not teach the claimed “making a substantially longitudinal incision in a wall of the graft vessel at an end thereof to form a flap therein.” In addition, Barak does not suggest “making a substantially longitudinal incision in a wall of the graft vessel,” whether to form a flap or otherwise. The Office Action speculates that a longitudinal incision in the graft vessel “would aid in attaching the graft vessel to the graft affixer because the distal end would become slightly more dilated.” (Office Action, page 3). This rationale is incorrect for at least three reasons. First, the end of the graft vessel of Barak is everted over the distal end of two tongs or anvil halves. (Barak; e.g., Figures 3C, 8). If an incision were present in the end of the graft vessel, the everted cuff would exert less compressive force on the tongs or anvil, such that it would be more likely to slip off. That is, the portion of the graft vessel distal to the incision would be incapable of exerting compressive force on the tongs or anvil due to the interruption of the circular cross-section of the graft vessel. This would be contrary to a purpose of Barak, set forth in the Summary of the Invention, that the end of the graft vessel is “everted into a snugly-fitted cuff.” (Barak; col. 1, lines 64-67). The incision would reduce the snugness of the fit between the cuff and the tongs. Second, a longitudinal incision at the end of the graft vessel would result in leakage at the anastomosis site of Barak. Barak creates a circular anastomosis by inserting the distal end of the graft vessel into the opening in the target vessel. (Barak; Figures 3E, 3F, 10E, 10F). Any longitudinal incision at the end of the graft vessel would create a leak path at the anastomosis site, which Barak seeks to prevent. (Barak; col. 3, lines 42-45). Third, a longitudinal incision at the end

of the graft vessel would interrupt the topology of Barak, the stated purpose of which is that it provides for endothelium-to-endothelium contact between the graft and target vessels. (Barak; e.g., col. 4, lines 11-19). Further, whether as a result of an incision or not, Barak nowhere teaches or suggests a flap at any location on the graft vessel, much less at an end of the graft vessel. Indeed, the Office Action does not contend that Barak teaches or discloses forming a flap in the graft vessel; the Office Action is silent as to this limitation of claim 1. (Office Action, pages 2-3).

Second, amended claim 1 additionally requires “placing the flap against an outer surface of the target vessel.” Nowhere does Barak teach or suggest placing a flap, or any part of the graft vessel, against an outer surface of the target vessel. Barak instead discloses, for each embodiment, inserting the everted cuff at the end of the graft vessel through an opening in the target vessel and into the lumen of the target vessel. (Barak; col. 3, lines 61-66; col. 5, lines 42-45; col. 7, lines 41-48; Figures 3E, 10B-10F). Further, as stated above, the topology of the anastomosis of Barak provides endothelium-to-endothelium contact between the graft and target vessels – not contact between the endothelium of the graft vessel and the outer surface of the target vessel. As a result, Barak fails to teach, and indeed teaches away from, placing a flap of the graft vessel against an outer surface of the target vessel.

Thus, Barak does not teach or suggest all of the limitations of amended claim 1, and claim 1 is believed to be in condition for allowance. Claims 2-3, 5-10, 12-13 and 30-34 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 3, the specification of the present application expressly defines the heel of the anastomosis as the “end of the anastomosis...at which the outer surface of the graft vessel 404 forms an acute angle with the outer surface of the target vessel.” (Specification; page 99, lines 11-16; Figure 73). “Where an explicit definition is provided by the application for a term, that definition will control interpretation of the term as it is used in the claim.” (MPEP 2111.01(IV)). Thus, for the anastomosis to have a heel as claimed, the graft vessel must be angled at

other than a right angle relative to the target vessel, or else the outer surface of the graft vessel could not form an “acute angle” with the target vessel. In contrast, Barak describes connections between a graft vessel and a target vessel at a 90 degree angle, such that no acute angle is formed between the graft vessel and the target vessel. (Barak; Figures 3F, 10F). As a result, the anastomosis of Barak does not have a heel as the term is used in claim 3.

With regard to dependent claims 8-9, Barak does not disclose the claimed “measurement feature,” nor the claimed “angling the graft vessel relative to the staple holder until one side of the graft vessel is positioned substantially at one end of said measurement feature and the other side of the graft vessel is positioned substantially at the other end of said measurement feature.” The distal end of the graft vessel is simply everted onto the distal end of the tongs 5 of Barak. (Barak, Figure 3C). Barak neither teaches nor suggests angling the graft vessel relative to those tongs. (Barak; col. 5, lines 52-56). Indeed, the staple cartridges of Barak are nowhere near the tongs 5 during that eversion, such that Barak neither teaches nor suggests the claimed “angling the graft vessel relative to the staple holder.” Further, contrary to the assertion of the Office Action, Barak neither teaches nor suggests using “anvil ports” as a measurement feature; that term appears nowhere in Barak.

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,

/Brian A. Schar, Esq./

Brian A. Schar, Esq.
Reg. No. 45,076
Director of Intellectual Property
Cardica, Inc.
Tel. No. (650) 331-7162